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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

NOVARTIS CORPORTION, NOVARTIS PHARMACEUTICALS CORPORATION and NOVARTIS INTERNATIONAL AG, Plaintiffs, v. LUPIN LTD. and LUPIN PHARMACEUTICALS, INC. Defendants.	Civil Action No. 06-5954 (HAA) **ANSWER AND COUNTERCLAIM**

Defendants, Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively "Lupin"), by way of Answer to the Complaint of Plaintiffs Novartis Corporation, Novartis Pharmaceuticals Corporation, and Novartis International AG (collectively "Novartis"), respond as follow:

THE PARTIES

Complaint Paragraph 1: Plaintiff Novartis Corporation is a New York corporation having a principal place of business at 180 Park Avenue, Florham Park, New Jersey.

Answer: With respect to paragraph 1 of the complaint, Lupin admits only that Novartis Corporation is a New York corporation with an address at 180 Park Avenue, Florham Park, New Jersey. Lupin is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 1, and therefore denies them.

Complaint Paragraph 2: Plaintiff Novartis Pharmaceuticals Corporation is a Delaware corporation having a principal place of business at One Health Plaza, East Hanover, New Jersey.

Answer: With respect to paragraph 2 of the complaint, Lupin admits only that Novartis Pharmaceuticals Corporation is a Delaware corporation with an address at One Health Plaza, East Hanover, New Jersey. Lupin is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 2, and therefore denies them.

Complaint Paragraph 3: Plaintiff Novartis International AG is a Swiss corporation having a principal place of business at Lichtstrasse 35, CH-4056, Basel, Switzerland.

Answer: With respect to paragraph 3 of the complaint, Lupin admits only that Novartis International AG is a Swiss corporation with an address at Lichtstrasse 35, CH-4056, Basel, Switzerland. Lupin is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 3, and therefore denies them.

Complaint Paragraph 4: On information and belief, Lupin Ltd. is an Indian corporation having a principal place of business at Laxmi Towers, B Wing, Bandra Kurla Complex, Mumbai, 400 051, India.

Answer: With respect to paragraph 4 of the complaint, Lupin admits only that Lupin Ltd. is an Indian corporation with a place of business at Laxmi Towers, B Wing, Bandra Kurla Complex, Mumbai, 400 051, India. Lupin denies the remaining allegations in paragraph 4.

Complaint Paragraph 5: On information and belief, Lupin Pharmaceuticals, Inc. is a wholly-owned subsidiary, agent, and alter-ego of Lupin Ltd., organized and existing under the laws of the State of Virginia, and has a principal place of business at Harborplace Tower, 111 South Calvert Street, Baltimore, Maryland 21202.

Answer: With respect to paragraph 5 of the complaint, Lupin admits only that Lupin Pharmaceuticals, Inc. is a Virginia corporation with its principal place of business at Harborplace Tower, 111 South Calvert Street, Baltimore, Maryland 21202 and that Lupin Pharmaceuticals, Inc. is a wholly owned subsidiary of Lupin Ltd. Lupin denies the remaining allegations in paragraph 5.

JURISDICTION AND VENUE

Complaint Paragraph 6: This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338.

Answer: With respect to paragraph 6 of the complaint, Lupin admits that Novartis purports to base jurisdiction on 28 U.S.C. §§ 1331 and 1338. Lupin denies the remaining allegations in paragraph 6, and expressly denies any infringement and that Novartis is entitled to any relief.

Complaint Paragraph 7: On information and belief, Lupin Ltd. and Lupin Pharmaceuticals, Inc. are in the business of making and selling generic drug products.

Answer: Lupin admits the allegations in paragraph 7 but denies that Lupin Pharmaceuticals, Inc. makes generic drug products.

Complaint Paragraph 8: On information and belief, Lupin Ltd. and Lupin Pharmaceuticals, Inc. conduct business in the State of New Jersey and sell various drug products in the United States, including the State of New Jersey.

Answer: With respect to paragraph 8 of the complaint, Lupin admits only that Lupin Pharmaceuticals, Inc. sells various drug products in the United States. Lupin denies the remaining allegations in paragraph 8.

Complaint Paragraph 9: On information and belief, Lupin Ltd. manufactures generic drugs for sale and use throughout the United States, including the State of New Jersey, alone and/or through its wholly-owned subsidiary, agent, and alter-ego Lupin Pharmaceuticals, Inc.

Answer: With respect to paragraph 9 of the complaint, Lupin admits only that Lupin Ltd. manufactures generic drugs for sale and use in the United States. Lupin denies the remaining allegations in paragraph 9.

Complaint Paragraph 10: On information and belief, Lupin Ltd. and Lupin Pharmaceuticals, Inc. have in the past been sued in the United Sates District Court for the District of New Jersey.

Answer: Lupin admits the allegations in paragraph 10.

Complaint Paragraph 11: Upon information and belief, Lupin Pharmaceuticals, Inc. is registered to do business in New Jersey as a foreign profit corporation, with business identification number 0100953673.

Answer: Lupin admits the allegations in paragraph 11.

Complaint Paragraph 12: Upon information and belief, Lupin Pharmaceuticals, Inc. has appointed National Registered Agents, Inc. of Princeton, New Jersey, as its registered agent for the receipt of service of process.

Answer: Lupin admits the allegations in paragraph 12.

Complaint Paragraph 13: Lupin Ltd. and Lupin Pharmaceuticals, Inc. are subject to personal jurisdiction in this District.

Answer: Lupin denies the allegations in paragraph 13, but Lupin will not contest personal jurisdiction in New Jersey for purposes of this action.

Complaint Paragraph 14: Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

Answer: Lupin denies the allegations in paragraph 14, but Lupin will not contest venue in this judicial district for purposes of this action.

The '802 Patent

Complaint Paragraph 15: On December 19, 2000, the United States Patent and Trademark Office (the "PTO") duly and lawfully issued United States Patent No. 6,162,802 (the "'802 patent"), entitled "Synergistic Combination Therapy Using Benazepril and Amlodipine for the Treatment of Cardiovascular Disorders and Compositions Therefor." The '802 patent has been assigned to, and continues to be owned by, Novartis Corporation. The '802 patent will expire on December 19, 2017. A copy of the '802 patent is attached hereto as Exhibit A.

Answer: With respect to paragraph 15 of the complaint, Lupin admits only (a) that the '802 patent is entitled "Synergistic Combination Therapy Using Benazepril and Amlodipine for the Treatment of Cardiovascular Disorders and Compositions Therefor," (b) that the assignment records at the PTO identify Novartis Corporation as the assignee of the '802 patent, (c) that the '802 patent expires on December 19, 2017, and (d) that a document purporting to be the '802 patent is attached to the complaint. Lupin denies the remaining allegations in paragraph 15, and specifically denies that the PTO duly and lawfully issued the '802 patent.

Complaint Paragraph 16: Novartis Corporation exclusively licensed the '802 patent to Novartis International AG, which in turn exclusively licensed the '802 patent to Novartis Pharmaceuticals Corporation.

Answer: Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 19, and therefore denies them.

Complaint Paragraph 17: The '802 patent is directed to and claims, inter alia, a pharmaceutical composition consisting essentially of a range of ratios of specified amounts of benazepril and amlodipine (or pharmaceutically acceptable salts of either or both), as well as a method of treating a condition selected from a group consisting of, inter alia, hypertension, in a human, consisting of administering a daily dose of a range of ratios of specified amounts of benazepril and amlodipine (or pharmaceutically acceptable salts of either or both).

Answer: With respect to the allegations of paragraph 17 of the complaint, Lupin admits (a) that claim 1 of the '802 patent concerns a method of treating a human with a condition "selected from the group consisting of hypertension, congestive heart failure, angina, myocardial infarction, artheroscierosis, diabetic nephropathy, diabetic cardiac myopathy, renal insufficiency, peripheral vascular disease, left ventricular hypertrophy, cognitive dysfunction, stroke, and headache" by administering benazepril or a pharmaceutically acceptable salt form and amlodipine or a pharmaceutically acceptable salt form in certain amounts and (b) that claim 19 of the '802 patent concerns a pharmaceutical composition consisting essentially of a daily dose of certain amounts of benazepril or a pharmaceutically acceptable salt form and amlodipine or a pharmaceutically acceptable salt form "such that the benazepril and the amlodipine are physically separated from one another." Lupin denies the remaining allegations in paragraph 17.

Lotrel®

Complaint Paragraph 18: Novartis Pharmaceuticals Corporation holds an approved New Drug Application for amlodipine and benazepril hydrochloride combination capsules, in 2.5/10 mg (amlodipine/benazepril hydrochloride), 5/10 mg, 5/20 mg, 10/20 mg, 5/40 mg, and 10/40 mg dosage strengths, which it sells under the brand name Lotrel®.

Answer: With respect to paragraph 18 of the complaint, Lupin admits only that Novartis Pharmaceuticals Corporation holds an approved New Drug Application for amlodipine besylate and benazepril hydrochloride combination capsules, in 2.5/10 mg, 5/10 mg, 5/20 mg, 10/20 mg, 5/40 mg, and 10/40 mg dosage strengths, which it sells under the brand name Lotrel®. Lupin denies the remaining allegations in paragraph 18.

Complaint Paragraph 19: Pursuant to 21 U.S.C. §§ [sic] 355(b)(1) and attendant United States Food and Drug Administration ("FDA") regulations, the '802 patent is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Lotrel®.

Answer: With respect to paragraph 19 of the complaint, Lupin admits only that Novartis listed the '802 patent in the Orange Book with respect to Lotrel®. Lupin denies the remaining allegations in paragraph 19.

Lupin's ANDA and Amendment

Complaint Paragraph 20: On information and belief, Lupin submitted Abbreviated New Drug Application ("ANDA") No. 78-466 to the FDA pursuant to 21 U.S.C. § 355(j) (the "Lupin ANDA"), and subsequently an amendment thereto (the "Lupin Amendment"), seeking approval to market amlodipine besylate and benazepril hydrochloride capsules (the "Lupin Product"). On

information and belief, Lupin Ltd. designated Lupin Pharmaceuticals, Inc. as its United States agent in connection with the Lupin ANDA and the Lupin Amendment.

Answer: Lupin admits the allegations in paragraph 20.

Complaint Paragraph 21: On information and belief, the Lupin ANDA and the Lupin Amendment refer to and reply upon Novartis' NDA for Lotrel® and purport to contain data showing bioequivalence of the Lupin Product with Lotrel®.

Answer: Lupin admits the allegations in paragraph 21.

Complaint Paragraph 22: Novartis received from Lupin a letter, dated October 30, 2006, and attached memorandum (collectively, the "First Lupin Notification"), stating that Lupin filed the Lupin ANDA seeking approval to market the Lupin Product in 2.5 mg/10 mg, 5 mg/10 mg, 5 mg/20 mg, and 10 mg/20 mg dosage strengths.

Answer: Lupin admits the allegations in paragraph 22.

Complaint Paragraph 23: Novartis received from Lupin a letter, dated November 29, 2006, and attached memorandum (collectively, the "Second Lupin Notification"), stating that Lupin filed the Lupin Amendment seeking approval to market the Lupin Product in 5 mg/40 mg and 10 mg/40 mg dosage strengths.

Answer: Lupin admits the allegations in paragraph 23.

Complaint Paragraph 24: By the First Lupin Notification and the Second Lupin Notification, Lupin states that, pursuant to section 21 U.S.C. § 355(j)(2)(A)(vii)(IV), the Lupin ANDA and the Lupin Amendment certify that the '802 patent is invalid and/or will not be infringed by the manufacture, use, offer of sale, or sale of the Lupin Product.

Answer: Lupin admits the allegations in paragraph 24.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 6,162,802

Complaint Paragraph 25: Novartis hereby realleges and incorporates by reference the allegations of paragraphs 1-24 of this Complaint.

Answer: With respect to paragraph 25 of the complaint, Lupin repeats and incorporates by reference paragraphs 1 through 24 of the answer as if fully set forth herein.

Complaint Paragraph 26: Lupin has infringed, induced the infringement, and contributed to the infringement of the '802 patent pursuant to 35 U.S.C § 271(e)(2)(A) by submitting to the FDA ANDA No. 78-466, and the Lupin Amendment, which each include a Paragraph IV Certification as to the '802 patent and which seek approval from the FDA to engage in the commercial manufacture, use, or sale of the Lupin Product prior to the expiration of the '802 patent.

Answer: Lupin denies the allegations in paragraph 26, but admits that the Lupin ANDA and the Lupin Amendment included Paragraph IV Certifications as to the '802 patent.

Complaint Paragraph 27: On information and belief, Lupin has knowingly and willfully infringed the '802 patent.

Answer: Lupin denies the allegations in paragraph 27.

Complaint Paragraph 28: Novartis will be irreparably harmed if Lupin is not enjoined from infringing the '802 patent.

Answer: Lupin denies the allegations in paragraph 28.

DEFENSES

Without any admission as to the burden of proof or as to any of the averments in the complaint, Lupin sets forth the following defenses:

First Defense

The '802 patent claims do not cover the Lupin Product, and therefore Lupin has not infringed, does not infringe, and would not infringe the '802 patent if it made, used, sold, offered for sale, marketed, or imported that product.

Second Defense

The '802 patent and all its claims are invalid under 35 U.S.C §§ 102, 103, and/or 112.

WHEREFORE defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc. demand judgment dismissing the complaint with prejudice, for costs of suit, for reasonable attorney fees, and such other relief as the Court deems just and proper.

COUNTERCLAIM

Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively "Lupin") by way of Counterclaim against Novartis Corporation, Novartis Pharmaceuticals Corporation, and Novartis International AG (collectively "Novartis"), say:

PARTIES/JURISDICTION

1. Lupin Pharmaceuticals, Inc. is a Virginia corporation with its principal place of business at Harborplace Tower, 111 South Calvert Street, Baltimore, Maryland 21202.

2. Lupin Ltd. is an Indian corporation with an address at Laxmi Towers, B Wing, Bandra Kurla Complex, Mumbai, 400 051, India.

3. On information and belief, Novartis Corporation is a New York corporation with an address at 180 Park Avenue, Florham Park, New Jersey.

4. On information and belief, Novartis Pharmaceuticals Corporation is a Delaware corporation with an address at One Health Plaza, East Hanover, New Jersey.

5. On information and belief, Novartis International AG is a Swiss corporation with an address at Lichtstrasse 35, CH-4056, Basel, Switzerland.

6. These claims arise under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Lupin seeks declaratory relief, i.e., a declaration that the patent in suit is not infringed and that it is invalid.

7. This Court has original jurisdiction over the subject matter of these claims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

FACTUAL BACKGROUND

8. United States Patent No. 6,162,802 (the "'802 patent"), entitled "Synergistic Combination Therapy Using Benazepril and Amlodipine for the Treatment of Cardiovascular Disorders and Compositions Therefor," issued on December 19, 2000.

9. On information and belief, the assignment records at the United States Patent and Trademark Office show that the '802 patent was assigned to Novartis Corporation.

10. The '802 patent concerns cardiovascular-disorder therapy and discloses amlodipine (and its pharmaceutically acceptable salts) and benazepril (and its pharmaceutically acceptable salts) as active ingredients.

11. Lupin submitted Abbreviated New Drug Application ("ANDA") No. 78-466 and an amendment thereto, seeking approval to market capsules containing amlodipine besylate and benazepril hydrochloride as active ingredients.

FIRST COUNT
(Declaration of Noninfringement)

12. Lupin repeats the allegations contained in paragraphs 1 through 11 of the counterclaim as if fully set forth herein.

13. The '802 patent claims do not cover Lupin's proposed amlodipine besylate and benazepril hydrochloride capsules. Therefore, Lupin has not infringed, does not infringe, and

would not infringe the '802 patent if it made, used, sold, offered for sale, marketed, or imported its proposed product.

14. Novartis has asserted the '802 patent against Lupin. Novartis maintains—and Lupin denies—that the '802 patent claims cover Lupin's proposed amlodipine besylate and benazepril hydrochloride capsules.

15. There is an actual, substantial, and continuing justiciable controversy between Lupin and Novartis regarding the infringement of the '802 patent.

16. Lupin is entitled to a judicial declaration that any making, use, sale, offer for sale, marketing, or importation of its proposed amlodipine besylate and benazepril hydrochloride capsules has not infringed, does not infringe, and would not infringe the '802 patent.

SECOND COUNT
(Declaration of Invalidity)

17. Lupin repeats the allegations contained in paragraphs 1 through 11 of the counterclaim as if fully set forth herein.

18. The '802 patent and all its claims are invalid under 35 U.S.C. §§ 102, 103, and/or 112.

19. Novartis maintains—and Lupin denies—that the '802 patent claims are valid.

17. There is an actual, substantial, and continuing justiciable controversy between Lupin and Novartis regarding the validity of the '802 patent claims.

18. Lupin is entitled to a judicial declaration that the '802 patent claims are invalid.

WHEREFORE, Lupin demands judgment in its favor and against Novartis as follows:

(a) Dismissing the complaint with prejudice and denying each request for relief made by Novartis;

(b) Declaring the '802 patent not infringed by the filing of Lupin's ANDA;

(c) Declaring the '802 patent not infringed by any making, use, sale, offer for sale, marketing, or importation of Lupin's proposed amlodipine besylate and benazepril hydrochloride capsules;

(d) Declaring the '802 patent and all its claims invalid;

(e) Enjoining Novartis Corporation, Novartis Pharmaceuticals Corporation, and Novartis International AG, their officers, agents, servants, employees, attorneys, and any person who acts in concert or participation with any plaintiff from threatening to assert or otherwise attempting to enforce the '802 patent against Lupin, its customers, suppliers, or anyone in privity with Lupin.

(f) Adjudging this to be an exceptional case under 35 U.S.C. § 285 and awarding Lupin its attorney fees;

(g) Awarding Lupin its costs and expenses; and

(h) Awarding Lupin such other and further relief as the Court deems just and proper.

CARELLA, BYRNE, BAIN, GILFILLAN,
CECCHI, STEWART & OLSTEIN
Attorneys for Defendants

By: /s/ James E. Cecchi
JAMES E. CECCHI

Dated: January 19, 2007

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